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TRANSMITTAL
FORM

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Total Number of Pages in This Submission

9

Application Number

10/571,414

Filing Date

MARCH 10, 2006

First Named Inventor

FRANK THEOBALD

Art Unit

1516

Examiner Name

Attorney Docket Number

R04209US (#90568)

ENCLOSURES (Check all that apply)

☐

Fee Transmittal Form

☐

Fee Attached

☐

Amendment/Reply

☐

After Final

☐

Affidavits/declaration(s)

☐

Extension of Time Request

☐

Express Abandonment Request

☐

Information Disclosure Statement

☐

Certified Copy of Priority Document(s)

☐Reply to Missing Parts/
Incomplete Application☐Reply to Missing Parts
under 37 CFR 1.52 or 1.53☐

Drawing(s)

☐

Licensing-related Papers

☐

Petition

☐Petition to Convert to a
Provisional Application☐Power of Attorney, Revocation
Change of Correspondence Address☐

Terminal Disclaimer

☐

Request for Refund

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After Allowance Communication to TC

☐Appeal Communication to Board
of Appeals and Interferences☐Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)☐

Proprietary Information

☐

Status Letter

☒Other Enclosure(s) (please identify
below):Return post card
LETTER W/ENGLISH TRANSLATION
OF IPRP

Remarks

Please charge any additional fees or credit any overpayment
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

D. Peter Hochberg Co., L.P.A.

Signature

Printed name

D. Peter Hochberg

Date

January 17, 2007

Reg. No.

24,603

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

Typed or printed name

Christine Kotran

Date

1/17/2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Frank Theobald et al.

Serial No.: 10/571,414

Filed: March 10, 2006 / Conf. No. 3449

Title: MEDICAL SKIN PATCHES WITH A CONTENT OF ESSENTIAL OILS FOR TREATING COLDS, AND PROCESSES FOR THEIR PRODUCTION

Examiner: / Art Unit: 1615

Attorney File: RO4209US (#90568)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-4150

LETTER

Sir:

For inclusion in the record of the referenced patent application is an English translation of the "International Preliminary Report on Patentability" as rendered with respect to PCT/EP2004/010046 from which this is a 371 application.

Respectfully submitted,

By: _____

D. Peter Hochberg
Reg. No. 24,603

DPH/SM/ck
Enc.

Certificate of Mailing

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I hereby certify that this document, and anything indicated as being attached or enclosed, is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date noted below.

Christine Kotran: Christine Kotran

Date: January 17, 2007

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

Eingegangen

FLACCUS, Rolf-Dieter
Bussardweg 10
50389 Wesseling
ALLEMAGNE

17. AUG. 2006

FRIST:.....

Date of mailing (<i>day/month/year</i>) 03 August 2006 (03.08.2006)	
Applicant's or agent's file reference LTS 2003/007 PCT	IMPORTANT NOTIFICATION
International application No. PCT/EP2004/010046	International filing date (<i>day/month/year</i>) 09 September 2004 (09.09.2004)
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al	

1. Transmittal of the translation to the applicant.

- ☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).
- ☒ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Agnes Wittmann-Regis
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 82 70

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2003/007 PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/010046	International filing date (day/month/year) 09.09.2004	Priority date (day/month/year) 11.09.2003
International Patent Classification (IPC) or national classification and IPC A61K9/70, A619/00, A61L15/44, A61L15/16, A61F13/02		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/010046

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-12 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-24 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/010046

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims 4, 14, 15, 22, 23 YES Claims 1-3, 5-13, 16-21, 24 NO
Inventive step (IS)	Claims YES Claims 1-24 NO
Industrial applicability (IA)	Claims 1-24 YES Claims NO
2. Citations and explanations (Rule 70.7)	
1.	<p>The present report makes reference to the following documents:</p> <p>D1: WO 01/78691A (LECTEC CORP; GOON DAVID J W (US); ROLF DAVID (US)) 25 October 2001 (2001-10-25)</p> <p>D2: US 6 090 403 A (BLOCK LESLIE L ET AL) 18 July 2000 (2000-07-18)</p> <p>D3: WO 01/89475 A.</p>
2. Novelty	
	<p>The present application fails to satisfy the requirements of PCT Article 33(1) because the subject matter of the claims lacks novelty (PCT Article 33(2)).</p>
2.1	<p>Document D1 discloses a therapeutic patch consisting of a porous backing layer and a therapeutic formulation containing a medicament, a support for said medicament, and a pressure-sensitive adhesive material (see D1, page 2, line 27 to page 3, line 3). The medicament is</p> <p>/...</p>

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

an antitussive, for example camphor, menthol, eucalyptus oil, thyme oil (see D1, page 6, line 24 to page 7, line 2), the polymer support is preferably karaya rubber (see D1, page 13, lines 10-20) and the adhesive may be, *inter alia*, a polyacrylate (see D1, page 13, lines 10-20).

D1 discloses a number of formulations that contain less than 5 wt.% of water. Formulations that contain 0 wt.% of water are also described. The patch used in the case of coughs can be stuck to the chest, neck, chin or upper lip such that the medicaments can be inhaled (see D1, page 17, lines 18-25).

- 2.2 Documents D2 and D3 describe patches in which the support is coated with a hydrophilic formulation for pressure-sensitive bonding, said formulation containing volatile oils. A composition in the form of an unguent is mentioned in D2 (see column 8) and D3 (see page 17), which composition consists of camphor, menthol, eucalyptus oil, glycerine, karaya rubber and a latex adhesive and can be applied to a support without dilution. Since the sum of the components of the unguent is 100 wt.%, and since the unguent can be applied to the support without further dilution, it can be assumed that the water content of the unguent is very small.

/...

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Said unguent is produced by mixing the components in the presence of water or of a non-polar solvent, the latter being preferred (see D2, column 7, lines 50-60; D3, page 16, lines 17-19). The patch is used for disorders such as the common cold, a soothing effect being produced by the inhalation of the aromatic oils.

Thus, documents D1, D2 and D3 anticipate the novelty of claims 1-3, 5-13, 16-21 and 24.

3 Inventive step

The present application describes medical skin patches constituting hydrophilic, topical, anhydrous systems that are suitable for the delivery of volatile oils and are used for the treatment of disorders such as the common cold.

Although patches of this type have already been described in the prior art, coating compounds such as those according to claims 22 and 23 of the application have not been mentioned. Since said coating compounds differ from the formulations according to the prior art only by virtue of the quantity or concentration of the components used, and in the absence of any disclosure of a surprising technical effect that might be attributable to the use of different quantities, claims 22 and 23 are considered to be an obvious variation and modification of known formulations.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/010046

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

The method parameters specified in claims 14 and 15 are not mentioned in the prior art. The temperature variation is normal in the development of a new method. Adjusting the pot life, which - as stated in the application - is dependent on the water content of the coating compound, is also a routine measure.

Thus, the application does not involve an inventive step within the meaning of PCT Article 33(3).